

## **REMARKS**

The final Office Action of December 26, 2007, has been received and carefully considered. Applicants note that the Examiner has withdrawn the rejection of claim 23 as anticipated by USP 5,376,085 to Conway et al. ('the '085 patent') in response to Applicants' previous amendment.

### Claim Objections

The Examiner objected to claims 35 and 40 as depending from cancelled claim 24. Applicants have amended the claims to depend from claim 23.

### Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 23, 25-27, 35, 39, 44, 45, 47 and 48 under 35 U.S.C. § 103(a), as being unpatentable over USP 5,554,141 to Wendler ("Wendler") in view of EP 1,062,957 to Oda et al. ("Oda"), USP 5,417,981 to Endo et al. ("Endo"), USP 4,710,532 to Hull et al. ("Hull") and USP 6,520,934 to Lee et al. ("Lee"). The Examiner states that Wendler teaches an external urinary catheter having a sheath and tip and having a thermoplastic construction, but is silent as to the catheter's specific plasticizer and copolymer materials. According to the Examiner, Oda teaches a flexible, elastic and transparent device including a catheter made of styrene and ethylene copolymer and a plasticizer, to which other polymeric compounds could be added. The Examiner also states that Endo teaches catheters having ethylene-polypropylene-diene terpolymers. The Examiner offers Hull for teaching catheters using citrate plasticizers, and offers Lee for teaching catheters using polyamide-polyethylene block copolymer. The Examiner concludes that it would have been obvious at the time the invention was made, to use the plasticizers and polymers of Oda, Endo, Hull and Lee patents, in the catheter of Wendler in order to provide materials in the art known to be suitable for that purpose. Applicants respectfully traverse this rejection.

The U.S. Patent and Trademark Office issued examiner guidelines (72 Fed. Reg. 57526) for determining obviousness under the U.S. Supreme Court's ruling in KSR International Co. v. Teleflex, Inc., 82 USPQ2d 1385 (2007). The Examiner has framed the rejection as simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement, citing KSR. However, Applicants submit that the Examiner's rejection is a conclusory statement based on hindsight.

"Most, if not all, inventions are combinations and mostly of old elements." Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983). "An Examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerasonic Corp., 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996). See also, In re Rouffet, 149 F.3d 1350, 1357-58, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998)(...To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness).

At the time the invention was made, Applicants were attempting to improve an external urinary catheter by increasing the permeability of the catheter to water vapor. Applicants submit that under KSR, the proper question to ask, is whether one of ordinary skill in the urinary catheter art, when facing the needs in the field, i.e. looking to improve breathability or permeability, would have been motivated to look at improving the breathability of the external catheter of Wendler (a thermoplastic polymer urisheath), by looking at the teachings of Oda and Endo et al., Hull et al. and Lee et al., at the time of the invention?

A close inspection of the secondary references cited by the Examiner reveals that each one (Oda, Endo, Hull and Lee) is directed to medical devices designed for internal or intravenous use and compatible with blood or bodily fluids, and not to external urinary catheters or similar external devices (such as ostomy appliances) as in Applicants' claimed invention. None of the cited references teach or suggest how to improve the permeability of the thermoplastic polymers used to make an external urinary catheter or of any catheter type device.

For example, Oda, at paragraphs [0002] and [0005], teaches tubes for use in intravenous injection, catheters and bags or containers for blood, infusion solutions and other fluids. The plastics of these devices have to be biocompatible, and in particular, compatible with blood and bodily fluids. Furthermore, Oda refers to catheters, specifically balloon catheters used for angioplasty, and gastric catheters used for feeding. In paragraph [0017] the specification teaches that the plastic should have a low transition temperature so that it is flexible when percutaneously inserted into the body. The only mention of urinary devices is within a laundry list of other devices that are tube-like, and that can be inserted into a body cavity (page 11). Moreover, all the examples in Oda are directed to blood bags and intravenous catheters. There is no mention in Oda of the permeability of the polymer composition.

Endo was offered by the Examiner for teaching an ethylene-polypropylene-diene terpolymer used in a catheter. However, a glimpse of the abstract shows that Endo is teaching a thermoplastic polymer containing a protease inhibiting compound and medical devices made with the enzyme containing polymer. The protease inhibiting property is directed at inhibiting thrombin, which is a clotting protein in blood. Furthermore, Endo teaches that the devices of this patent include all things used for medical care which have the surfaces put in contact with blood and therefore need the compatibility with blood, particularly anti-thrombotic property, such as artificial organs and their circuit tubes, etc. (col. 5, lines 43-50). There is no mention of urinary devices, nor is there any mention of permeability of the polymer composition.

The Examiner cites Hull for teaching citrate plasticizers. The citrate plasticizers taught in Hull are within the context of polyvinylchloride based plastics (PVC) for medical uses, not polyamide-polyether block copolymers as claimed by Applicants. Again, as with Endo and Oda, the devices in which the PVC polymer compositions are directed, are intravenous tubes, blood storage, intra-arterial catheters, dialysis machines and so forth, and not external urinary catheters. There is also no mention of permeability of the polymer composition of Hull.

Finally, in Lee, as in Oda, the specification is directed to intra-arterial catheters with a radiopaque marker fixed to the shaft. The Examiner argues that Lee teaches catheters with polyamide-polyethylene block copolymers. Close reading of Lee reveals that the polymer is a polymer coating on the coiled radiopaque marker, used to keep the wire in the catheter from fraying. The polymers in the coating of Lee are not used in the construction of the catheter, let alone an external urinary catheter. In addition, there is no mention of permeability of the polymer composition.

All four of the secondary references cited by the Examiner relate to intravascular catheters or other cardiovascular devices in direct contact with blood. Applicants' invention is directed to external urinary catheters, which are an entirely different technical field, with essentially different purposes and physical demands on the properties of the compositions from which the devices are made.

None of the four secondary references teach or suggest the problem being solved by Applicants, namely improved permeability of the polymers which comprise the external urinary catheter. None of the references even teach that the combination of Applicants' claimed features would or could improve the permeability of the claimed polymer composition.

Applicants submit that the combination of Wendler, in view of Oda, Hull, Endo and Lee, cannot be considered to render Applicants' claimed invention obvious under the above rationale for support of rejections under 35 U.S.C. §103(a), according to KSR, because all of the rationales

recited in KSR require a credible and predictable outcome, or result, which cannot be found in any cited reference. There is no teaching or suggestion in any of the cited references, that adding the plasticizer and polymers of Oda, Hull, Endo and Lee to the urisheath of Wendler, would result in the urinary catheter having the properties claimed by Applicants. Thus, one of ordinary skill in the urology or urinary catheter arts, at the time the invention was made, would not have been motivated to look to technology in the cardiovascular arts, and in intravenous catheter art specifically, to find a way of increasing permeability in an external urinary catheter, particularly when none of the references show how one would have solved this problem.

Applicants respectfully point out that under the KSR guidelines, the Examiner's analysis supporting an obviousness rejection should be explicit. Such rejections, under KSR, cannot be sustained by mere conclusory statements. There must be some articulated reasoning with rational underpinnings to support the legal conclusion of obviousness. Applicants submit that in view of facts surrounding each of the secondary references, the Examiner's statements that Applicants' invention is "merely a simple substitution of known elements", or "the mere application of a known technique to a piece of prior art ready for improvement" are conclusory. There is no factual underpinning supporting the Examiner's statements as the Examiner did not show how one of ordinary skill would have predicted the outcome of Applicants' claimed invention, or how the combination of elements would improve permeability of the thermoplastic polymer in an external urinary catheter based on the facts present in the references. Moreover, KSR did not remove the obligation of the Examiner to show the suggestion or motivation of one of ordinary skill to combine the cited references, as stated in Ex parte Clapp, 227 U.S.P.Q. 972 (B.P.A.I. 1985).

Applicants respectfully put forth that the Examiner appears to be using hindsight and Applicants' own disclosure to make the *prima facie* case. The Examiner has failed to show how one of skill in the art would have been motivated to combine the teachings of Wendler, in view of Oda, Hull, Endo and Lee, to arrive at Applicants' claimed invention, and therefore Applicants respectfully request that the rejection be withdrawn.

The Examiner also rejected claims 28-32, 36-38, 40-43, 46, 49 and 50, under 35 U.S.C. § 103(a), as being unpatentable over Wendler, in view of Oda, Hull, Endo and Lee, and further in view of Stehr et al. (WO 96/29962) (“Stehr”). According to the Examiner, neither Wendler nor Oda, Hull, Endo or Lee disclose a catheter with a tip made separately from the sheath. The Examiner offers Stehr for teaching a condom catheter having a sheath and tip which are manufactured separately. The Examiner therefore concludes that it would have been obvious at the time the invention was made, to combine the teachings of Wendler, in view of Oda, Hull, Endo and Lee, with Stehr, in order to make a catheter having different properties in the sheath portion and the tip portion. Applicants traverse this rejection.

As Applicants stated with regard to the previous rejection, there is no teaching or suggestion in any of the cited references, that adding the plasticizer and polymers of Oda, Hull, Endo and Lee to the urisheath of Wendler, would result in the urinary catheter having the properties claimed by Applicants. Thus, one of ordinary skill in the urology or urinary catheter arts, at the time the invention was made, would not have been motivated to look to technology in the cardiovascular arts, and in intravenous catheter art specifically, to find a way of increasing permeability in an external urinary catheter, particularly when none of the references show how one would have solved this problem.

This deficiency is not cured by the addition of Stehr. Stehr only teaches condom catheters made of polyurethane. Stehr teaches a dipping process that allows for a thinner polyurethane urisheath having increased breathability due to its thinness. There is no teaching or suggestion in Stehr about finding a way of increasing permeability in an external urinary catheter using the polymers or plasticizers in Applicants’ invention. Thus, the Examiner has failed to show how one of skill in the art would have been motivated to combine the teachings of Wendler, in view of Oda, Hull, Endo and Lee, and further in view of Stehr, to arrive at Applicants’ claimed invention. Applicants respectfully request that this rejection be withdrawn.

It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Furthermore, as

Serial No.: 10/520,817  
Attorney Docket No.: P70346US0  
Page 12

Applicants have not raised any new issues in this response, Applicants submit that this is a proper response after final rejection and should be entered by the Examiner. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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